510(k) Summary
Orthopedic Sciences, Inc.
OSI Q System Arthroscopes
K133018

February 18, 2014

ADMINISTRATIVE INFORMATION

Manufacturer Name	Orthopedic Sciences, Inc. 3020 Old Ranch Parkway, Suite 325 Seal Beach, CA 90740 Telephone: +1 (562) 799-5550 Fax: +1 (562) 799-5533
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	OSI Q System Arthroscopes
Common Name	Arthroscope
Classification Name	Arthroscope
Classification Regulations	21 CFR 888.1100, Class II
Product Code	HRX
Classification Panel	Orthopedic
Reviewing Branch	Joint Fixation Devices Branch Two (JFDB2)

INTENDED USE

OSI Q System Arthroscopes of appropriate size and length are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the hip, shoulder, knee, elbow, wrist, and ankle, and also to provide illumination and visualization during open and closed arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the joint.

Hip Diagnostic procedures may include:
Staging of avascular necrosis
Chondral injuries
Joint sepsis
Synovial chondomatosis
Unresolved hip pain
Labral tears

OSI Q System Arthroscopes of appropriate size and length also are indicated for visualization and performance of arthroscopic surgical procedures on various structures of the spine, including nerve roots, foramina, intervertebral discs and the surrounding spinal structures.

DEVICE DESCRIPTION

OSI Q System Arthroscopes are rigid, fixed arthroscopes with a wide-angle view and a rod lens imaging system with a fiber optic illumination system to provide visualization of various anatomic structures during diagnostic and operative arthroscopic procedures. OSI Q System Arthroscopes have surgical stainless steel shafts and lens housing for durability and are available with various angles of view. The optical components are sealed to provide a durable focusing mechanism. The arthroscopes may be attached to a video camera and are available in various sizes, diameters and lengths, to provide for differences in arthroscopic surgical site and surgeon preference. OSI Q System Arthroscopes have a working length of 175.5 mm to 212.5 mm, diameters ranging from 3.1 mm to 5 mm, an angle of view (direction of view) of either 30° or 70°, and a field of view of either 90° or 100°. Visualization sheaths are provided in three designs, with diameters of either 5 mm or 6.1 mm, an angle of view of 0°, 30°, or 70°, and working lengths ranging from 151 mm to 185.5 mm.

The arthroscope main body tube, insertion tube, and optic tube are all made from 304 stainless steel. The other patient contacting parts of the arthroscope are the objective window (sapphire), eutectic solder, and USP Class VI epoxy, and are the same materials used in the predicate OSI Arthroscopes (K091398). The visualization sheaths are made from 316 stainless steel.

Arthroscopes are provided non-sterile and are reusable. Visualization sheaths are provided sterile for single use only.

EQUIVALENCE TO MARKETED DEVICE

OSI Q System Arthroscopes are substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Orthopedic Sciences, Inc., Arthroscope, K091398, and

NuVasive, Inc., Spinal Arthroscope, K992782.

A summary of the indications for use and the technological characteristics of the subject device and the predicate devices is provided in the following table.

	Subject Device	Predicate Devices	
	OSI Q System Arthroscopes Orthopedic Sciences, Inc. K133018	Arthroscope Orthopedic Sciences, Inc. K091398	Spinal Arthroscope NuVasive, Inc. K992782
Indications for Use	OSI Q System Arthroscopes of appropriate size and length are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the hip, shoulder, knee, elbow, wrist, and ankle, and also to provide illumination and visualization during open and closed arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the joint. Hip Diagnostic procedures may include: Staging of avascular necrosis Chondral injuries Joint sepsis Synovial chondomatosis Unresolved hip pain Labral tears OSI Q System Arthroscopes of appropriate size and length also are indicated for visualization and performance of arthroscopic surgical procedures on various structures of the spine, including nerve roots, foramina, intervertebral discs and the surrounding spinal structures.	The Arthroscopes of appropriate size and length are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the hip, shoulder, knee, elbow, wrist, and ankle, and also to provide illumination and visualization during open and closed arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the joint. Hip Diagnostic procedures may include: Staging of avascular necrosis Chondral injuries Joint sepsis Synovial chondomatosis Unresolved hip pain Labral tears	The NuVasive *Spinal Arthroscope*, consisting of a rigid diagnostic arthroscope with outer sheath, is intended to achieve percutaneous vizualization of, and/or to assist in performing percutaneous surgical procedures on, the spinal nerve root, foramina, intervertebral disc, and the surrounding tissues of the spine via uniportal or biportal posterior or posterolateral approach, where anatomic restrictions permit percutaneous access. The device is intended for use in conjunction with the NuVasive *Guided Spinal Arthroscopy System* under real-time radiographic visualization via image-intensified C-arm fluoroscopy, but may also be employed independent of that system where it is compatible in diameter and length with other commercially available arthroscopic instruments, and with surgical need.
Arthroscope Features			
Diameter	3.1 mm, 4 mm, 5 mm	2 mm to 4 mm	5 mm (sheath)
Working Length, mm	175.5, 178, 179, 212.5	40 to 300	400
Angle of View	0°, 30°, 70°	30°	0°, 30°, 70°
Field of View	90°, 100°	100°	105°
Illumination	ACMI; Wolf/Dyonics, Storz/Olympus adapters	ACMI; Wolf/Dyonics, Storz/Olympus adapters	ACMI; Wolf, Storz adapters
Locking mechanism: Sheath/cannula-to-arthroscope	Storz style	J-lock	n/a
Resolution	8.98 line pairs/mm (Model AS-175)	8.98 line pairs/mm (Model AS-175)	n/a
Magnification	8.6 X total magnification at 10 mm (Model AS-175)	8.6 X total magnification at 10 mm (Model AS-175)	n/a
How Provided	Non-sterile, reusable	Non-sterile, reusable	Non-sterile, reusable

The subject device has the same intended use as the predicate devices, the same indications for use as the predicate K091398 (other than in the spine), and indications for use in the spine similar to those of the predicate K992782. The slight differences in the indications for use statements for the subject device and predicate devices are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and do not affect the safety and effectiveness of the device when used as labeled because the technological characteristics and features of the subject device are similar or identical to the predicate devices K091398 and K992782.

The subject device design, illumination and imaging characteristics, and materials are the same as those of the predicate device K091398. The subject device design includes the same ranges of physical dimensions (diameter, working length, angle of view) as the predicate devices.

No new nonclinical tests were submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence because the technological performance characteristics of the subject devices are the same as the predicate device K091398.

No clinical tests were submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence because the technological performance characteristics of the subject devices are the same as the predicate device K091398.

The subject device and both predicate devices are rigid, reusable arthroscopes and are provided non-sterile to the end user. The subject device cleaning and sterilization instructions (provided in the Directions for Use labeling) include the following: place the OSI Q System Arthroscope into a sterilization container that is FDA cleared for the specified gravity displacement cycle; double wrap the container with a sterilization wrap that is FDA cleared for the specified gravity displacement cycle; do not stack the sterilization containers; thoroughly clean the sterilization containers before use; and check that the sterilization container is visually clean, and if not, repeat the cleaning until the container is visually clean. The sterilization wrap used in the subject device sterilization validation testing was Sterisheet, manufactured by Arjo Wiggins Medical, Inc., cleared under K931202.

Any differences in the technological characteristics between the subject device and the predicate devices do not raise new issues of safety or efficacy. The data provided in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, OSI Q System Arthroscopes have the following similarities to the predicate devices:

have the same intended use,
use the same operating principle,
incorporate the same basic design,
incorporate the same or very similar materials, and
have similar packaging and are sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

Orthopedic Sciences Incorporated
Kevin A. Thomas, Ph.D.
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K133018
Trade/Device Name: OSI Q System Arthroscopes
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: February 12, 2014
Received: February 14, 2014

Dear Dr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133018

Device Name
QSI Q System Arthroscope

Indications for Use *(Describe)*
Device Name: OSI Q System Arthroscopes
OSI Q System Arthroscopes of appropriate size and length are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the hip, shoulder, knee, elbow, wrist, and ankle, and also to provide illumination and visualization during open and closed arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the joint.
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.02.25 08:45:23 -05'00'

For BSA

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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